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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,615	04/20/2007	Yuzuru Umeda	1691-0217PUS1	4241

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
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BASQUILL, SEAN M

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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07/27/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,615	<b>Applicant(s)</b> UMEDA ET AL.	
	<b>Examiner</b> Sean Basquill	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-12, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 15, 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 May 2009 has been entered.

### ***Priority***

2. Applicant's claim for the benefit of the prior-filed International Application PCT/JP04/014774 under 35 U.S.C 365(c) and Japanese Application 2003-346858 under 35 U.S.C 119 is acknowledged.

### ***Claim Objections***

3. Claims 2, 5, 6, 7, and 9 are objected to because of the following informalities: the word "keratoconjunctiva" appears to be misspelled as "keratoconjunctive." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1612

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 2-12, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,811,446 (hereinafter “Thomas”), in view of U.S. Patent 5,994,372 (hereinafter “Yaksh”), and U.S. Patent 5,116,868 (hereinafter “Chen”).

Thomas describes the treatment of a variety of disorders of the eye, particularly those associated with an inflammatory element, including allergic conjunctivitis, viral conjunctivitis, and blepharitis. (C.4, L.41 – C.5, L.26). This treatment is achieved by topical administration of a solution containing a therapeutically effective amount of histidine to reduce ocular inflammation. (C.3, L.44-50). Thomas also indicates that compounds known to have cell regeneration activity when topically applied to the eye, such as but not limited to alpha-hydroxybutyric acid and salts and derivatives thereof, are particularly preferred as additional components of the topical composition. (C.7, L.31-40). Thomas indicates that typical dosing regimens range from between about 2-8 drops per day, but may range to as high as 20 drops per day in some instances. (C.9, L.50-59).

Art Unit: 1612

Thomas does not describe the administration of beta-hydroxybutyric acid or salts thereof in the treatment of eye diseases.

Yaksh describes ophthalmic solutions for the delivery of ophthalmic therapeutics such as those patented by Chen, which includes between 10-20 mM D,L-sodium-beta-hydroxy butyrate among the ingredients. (C.64, L.12-28). Such solutions are indicated as particularly useful in treating inflammatory conditions of the eye, including but not limited to inflammatory conjunctivitis. (C.69, L.44-57).

Chen describes the use of an ophthalmic solution which contains 10-20 mM D,L-sodium-beta-hydroxy butyrate among the ingredients. (C.4, L.1-45). D,L-sodium-beta-hydroxy butyrate is classified by Chen as a "ketone body," energy-rich molecules recognized as a rich energy source for peripheral tissues. (C.2, L.28-46). Ophthalmic solutions containing ketone bodies, such as that described by Chen, permit the irrigated tissues to perform energy-dependent metabolic functions more readily. (C.3, L.43-55). Chen additionally describes this solution as providing the essential nutrient requirements for ocular tissues to promote a healthy epithelium. (C.7, L.11-30).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have used an ophthalmic solution containing ketone bodies such as D,L-sodium-beta-hydroxy butyrate in the treatment of eye diseases including allergic conjunctivitis, viral conjunctivitis, and blepharitis. One having ordinary skill in the art would have been motivated to do so because Thomas teaches the advantage of combining with their histidine composition those compounds or compositions which promote cell regeneration activity, which Yaksh and Chen indicate include D,L-sodium-beta-hydroxy butyrate.

Art Unit: 1612

As a matter of claim interpretation, the examiner considers the “wherein” clauses of Claims 2-9 as simply reciting the intended results of positively recited process steps, which are considered not significant in the construction of the claim.

### ***Conclusion***

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill

Application/Control Number: 10/574,615

Page 6

Art Unit: 1612

Art Unit 1612

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642